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Essential fracture and orthopaedic equipment lists in low resource settings: Consensus derived by survey of experts in Africa

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Essential fracture and orthopaedic equipment lists in low resource settings:

Consensus derived by survey of experts in Africa

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Abstract

Objectives: Low- and middle-income countries (LMICs) have a growing need for trauma and orthopaedic (T&O) surgical interventions. LMICs lack surgical resources and we aimed to develop recommendations for an essential list of equipment for three different level of care providers.

Setting: Online based questionnaire distributed to experts working in LMICs.

Participants: Twenty experts with trauma and orthopaedic experience from LMICs underwent two rounds of questionnaires. Feedback was given after each round of questionnaire.

Interventions: The Delphi method was used to achieve consensus on essential and desirable T&O equipment for LMICs. An online based questionnaire was distributed over 2 rounds with feedback to the experts after each round.

Results: After two rounds of questionnaire, recommendations for each level of care in LMICs included four essential equipment items for non-operative based providers; 27 essential equipment items for specialist providers with operative fracture care, and 46 essential equipment items for tertiary providers with operative fracture care and orthopaedic care.

Conclusion: These recommendations have the potential to improve T&O care in LMICs. The essential equipment lists provided here are reasonable and feasible for LMICs healthcare systems, ensuring limited funding is targeted optimally. The recommendations can help with planning and organising national T&O care to attain appropriate capacity in the different levels of provider.

Introduction

Surgery is an essential component of health care. Two thirds of the world's population do not have access to safe affordable and timely surgical care and 16.9 million people die from conditions that require surgical care each year. Most of these deaths are from low-income and middle-income countries (LMICs)¹². For every death from injury, many more people are living with disability, contributing to the vicious cycle of poverty and reduced productivity^{3 4}. Trauma kills more people than HIV/AIDS, malaria and tuberculosis combined. Injuries are mainly from road traffic accidents, and disproportionately affect the young population⁵. Considerable mortality and morbidity can be avoided with prompt and appropriate trauma and orthopaedic care.

From the WHO global health observatory data, LMICs had higher road traffic fatality rates per 100,000 population (24.1 and 18.4 respectively) compared to high-income countries (9.2)⁴.Lower extremity injury can be a devastating event in LMICs due to reduced access to modern orthopaedic care. Chagomerana *et al.* found mortality rate of 9.0% in patients treated with traction and mortality rate of 1.3% in patients treated with surgery in Malawi⁶. If all-cause-injury mortality can be reduced to the level in high-income countries, 50 million Disability Adjusted Life Years and \$786 billion could be saved annually⁵.

Some programmes have been introduced to improve road safety, along with education and training of health professionals, and these have addressed some of the inequality issues. However further work is needed to explore what resources are required to provide trauma and orthopaedic (T&O) care in LMICs⁷. Stephens *et al.* found only 58% of patients admitted with the intention of definitive T&O surgical care received surgery due to resource constraints⁸. Deficient surgical equipment and supplies often limit access to surgical care. There is a lack of recommendation on what essential equipment is required in health care systems with limited resources. To address this gap, we wanted to provide an expert consensus on the essential equipment that is required to provide T&O care at different levels of surgical providers in LMICs. Without the provision of appropriate equipment, training of national T&O surgeons and other healthcare providers can be wasteful as they are disempowered from caring for the injured by lack of equipment.

Aim

We aim to produce a reference list of essential and desirable equipment for T&O providers in LMICs. The list is intended to guide governments, healthcare providers, and donors regarding the necessary equipment to be able to provide timely and appropriate care of fractures and orthopaedic conditions encountered at facilities in LMICs in sub-Saharan Africa. Similar principles are likely to apply in LMICs outside Africa. We aim to provide an essential list of equipment which will be a core set of equipment required, as well as a list of desirable but not essential equipment, to give care providers advice on further useful equipment if they can go beyond the core essentials. We hope these lists will be available for all those who intervene in the supply chain management. Our aim is to produce a generic list with no company affiliation and allow health providers to purchase from companies in their range of affordability.

Method

We used the Delphi method for this study⁹ ¹⁰. A two-round Delphi study was used with a group of experts answering two web-based questionnaires through Google forms¹¹. The timing between the two questionnaires was 30 days¹².

We provided the experts with definitions of what we mean by equipment, essential equipment and desirable equipment.

Definitions

<u>'Equipment'</u> is a re-useable item which facilitates fracture and orthopaedic care, and is specific to T&O. We did not consider hospital furniture items unless they were specific to T&O care – for example a traction table for fracture surgery was included, but an operating table was not. We did not list consumable items, but some equipment listed requires appropriate consumables and it was understood that a supply of appropriate consumables would be required.

<u>'Essential equipment'</u> is an item of equipment considered to be essential by 75% or more of the experts who responded.

<u>'Desirable equipment'</u> is an item for which does not reach consensus for being an essential equipment but does achieve 75% or more when considering 'definitely' or' possibly include' together.

Three independent experts, each with over 15 years' experience in Trauma and Orthopaedic (T&O) surgery were asked to verify the definitions used for different levels of provider institution, and to generate a list of possible essential equipment for selection in the questionnaire. Definitions used for each tier of provider were as listed below:

Tiers of provider

'Non-operative based provider': such a centre would not have a specialist T&O surgeon, but care would be given by general doctors or paramedics such as Orthopaedic Clinical Officers (OCOs).

<u>'Specialist provider with operative fracture care'</u>: such a centre would have 1 to 3 T&O or General surgeons with specific training in operative fracture care. It may receive residents but would not oversee its own residency programme in T&O.

<u>'Tertiary provider with operative fracture care and orthopaedics':</u> such a centre would be a referral centre for T&O and a resident teaching centre as well. It would normally be staffed by 4 or more specialist T&O surgeons, with some available sub-specialty expertise (pelvic & acetabulum, hand surgery, etc.).

Spine and craniomaxillofacial (CMF) surgery were omitted as their inclusion would have been too broad.

A group of 34 trained T&O surgeons in Africa who serve regularly as faculty on fracture care education courses in LMICs were invited to answer the questionnaire. These selected experts work in 13 sub-Saharan African (SSA) countries. Eighteen works at a tertiary hospital level and 15 at

specialist provider level. From round 1, we received 23 responses from 11 different African countries. The respondents included 52.2% from specialist tertiary centres and 47.8% of respondents from specialist provider centres. We received 20 expert responses in round 2 from 10 different countries. The respondents included 55% from specialist tertiary centres and 45% of respondents from specialist provider centres.

The questionnaire was designed by one of the authors (WJH) who has 20 years of experience of T&O surgery in LMICs. The responses were analysed by YC who has no previous experience of or connections with T&O surgery in LMICs but is familiar with the Delphi technique. The responders were anonymous but were requested to identify their country of regular work. Experts were each assigned a number and kept their number throughout the process.

We sent out a web-based questionnaire explaining our aims and instructions as follows:

'Our aim is to produce an essential equipment list for fracture care and orthopaedic provider institutions. Please mark your preference from 'definitely exclude' to 'definitely include', against each equipment item for each of the three tiers of care-provider. It should be assumed that equipment would be accompanied by appropriate implants/consumables with an ongoing supply. Please do not leave any blanks. There is free text space where you can give suggestions of other essential equipment or indicate any questions that are not clear as well as to give reasoning for your response. If your response is neutral, please provide further feedback as to why.

The responses were graded by the experts on a 5-point Likert scale. The options on the scale were as follows: definitely exclude, possible exclude, neutral, possibly include, definitely include. 'Possibly include' and 'definitely include' were counted towards consensus. Responses 'definitely exclude' and 'possibly exclude' counted towards an item being dropped.

Criteria on consensus was defined as 75% of participants selecting 'definitely include' for an item a 5-point Likert scale. Criteria on dropping an item was defined as 75% of participants selecting 'definitely exclude' for an item on a 5-point Likert scale¹⁰. Items which did not fulfil either criterion were brought forward to the next phase with specific feedback on the lack of consensus reached for the item to try and clarify consensus. Thus, in round two the same questionnaire was proposed to the expert group minus all items which had 75% of experts selecting 'definitely exclude'. In addition, experts were now given feedback regarding which items had so far achieved 75% consensus for inclusion. The experts could select differently in the second round as their 'final decision' with the benefit of this reduced number of items & feedback on other expert opinion.

Quantitative data included the mean, median and the frequency distribution of each option for each item were sent to the participants after round 1. Thus, participants were able to see which items were heading towards being included in the essential or desirable equipment list as well as which items were going to be dropped. They had the opportunity to change their response in round 2 of the questionnaire.

In round 2, we specifically named which additional items were added from the expert suggestions after round 1.

After round 2, any items still left neutral at this point were now dropped. Items which reached 75% 'definitely include' were classed as essential equipment. Any item which did not reach 75%

'definitely include' but reached 75% consensus when 'definitely include' and 'possibly include' were counted together contributed to a list of desirable but not essential equipment. Equipment items for which opinion was sought have been listed on the main result table (see Table 1).

Patient and public involvement

No patient or public involvement was required in this study.

Results

Results from round 1

All the items were carried forward to the second round in the specialist provider and tertiary centre tiers of care. Only the non-operative based provider had 16 items excluded from round 1. We included 5 additional items for round 2 voting. These are shown as the last 5 equipment items in table 1.

Results from round 2

The final list of essential and desirable equipment for each tier is shown in table 2.

Items included in questionnaire	Non-	Specialist	Tertiary
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	operative	provider	provider
	provider	p. c	p. c
Traction operating table	N	D	E
C-arm image intensifier	N	E	E
3. Power drill - fully sterilisable	N	E	Е
4. Power saw - fully sterilisable	N	D	E
5. Power drill - handyman type	N	Е	D
(hardware store) with sterile			
cover			
6. Hand drill	D	D	D
7. T handle	D	E	E
8. Small fragment plating set	N	E	E
Large fragment plating set	N	E	E
10. Dynamic hip screw (DHS)	N	E	E
instrument set			
11. Hip hemiarthroplasty set	N	D	E
12. SIGN nailing set	N	E	E
13. Tibial nail set (not SIGN) –	N	D	E
locking			
14. Femoral nail set (not SIGN) –	N	D	E
locking			
15. Femoral reconstruction nail set	N	D	E
(not SIGN)			
16. Proximal femoral nail set (i.e.,	N	D	E
Gamma nail)			
17. Large cannulated screws	N	E	E
18. Small cannulated screws	N	D	E
19. Mini fragment (hand) plating	N	D	E
set			

20. Locking plating set (upper limb)	N	D	E
21. Locking plating set (lower limb)	N	D	E
22. Large external fixator set (lower limb)	N	E	E
23. Small external fixator set (upper limb)	N	E	E
24. Rush nail set	N	E	E
25. K-wire and cerclage wiring set	N	E	Е
26. Cable set with tensioners	N	D	E
27. Flexible nail set (for children's fractures)	N	D	E
28. Total hip replacement set	N	N	Е
29. Total knee replacement set	N	N	Е
30. Knee arthroscopy equipment	N	N	Е
31. ACL reconstruction equipment	N	N	D
32. Large basic orthopaedic set (including large size nibblers, bone cutters, osteotomes, mallet, forceps, retractors, needle holders)	N	E	E
33. Small basic orthopaedic set (including small size nibblers, bone cutters, osteotomes, toffee hammer, forceps, retractors, needle holders)	N	E	Е
34. Fine instrument soft tissue set (including small forceps, needle holders etc. suitable for hand surgery and similar)	N	E	E
35. Large fracture reduction clamp set	N	E	E
36. Small fracture reduction clamp set	N	E	E
37. Specific pelvic reduction clamps	N	D	E
38. Humby knife for harvesting split skin graft	N	E	E
39. Electric or air powered dermatome for harvesting split skin graft	N	D	E
40. Mesher for split skin graft	N	E	E
41. Traction pulleys	Е	E	E
42. Braun frame for limb elevation and traction	E	E	Е
43. Vacuum assisted wound closure – 'home made' with portable suction	N	E	E
44. Vacuum assisted wound closure – company purposemade version	N	D	Е

45. Large femoral distractor	N	D	E
46. Specialist radiolucent	N	D	E
operating table			
47. Electric plaster saw	E	E	E
48. Manual plaster saw	E	E	D
49. Gigli saw	N	E	E
50. Amputation set	N	E	Е

Table 1: Results after round 2 (N=not recommended; E=essential; D=desirable; blue highlighted items were added after round 1; grey highlighted items were excluded after round 1)



Essential equipment list		Desirable equipment list
Non-operative provider		
Electric plaster cast saw		Hand drill
Manual plaster cast saw		T handle
Traction pulleys		
Braun frame for limb elevation and traction		
Specialist provider		
C-arm image intensifier	Rush nail set	Traction operating table
Power drill - fully sterilisable	K-wire and cerclage wiring set	Specialist radiolucent table
Power drill – handyman type (hardware store) with	Large basic orthopaedic set (including large size	Power saw - fully sterilisable
sterile cover	nibblers, bone cutters, osteotomes, mallet, forceps,	Hand drill
Electric plaster cast saw	retractors, needle holders)	Hip hemiarthroplasty set
Manual plaster cast saw	Small basic orthopaedic set (including small size	Tibial nail set (not SIGN) - locking
Gigli saw	nibblers, bone cutters, osteotomes, toffee hammer,	Femoral nail set (not SIGN) - locking
T handle	forceps, retractors, needle holders)	Femoral reconstruction nail set (not SIGN)
Small fragment plating set	Fine instrument soft tissue set (including small	Proximal femoral nail set (i.e., Gamma nail)
Large fragment plating set	forceps, needle holders etc. suitable for hand surgery	Small cannulated screws
Dynamic hip screw (DHS) instrument set	and similar)	Mini fragment (hand) plating set
SIGN nailing set	Amputation set	Locking plating set (upper limb)
Large cannulated screws	Large fracture reduction clamp set	Locking plating set (lower limb)
Large external fixator set (lower limb)	Small fracture reduction clamp set	Cable set with tensioners
Small external fixator set (upper limb)	Humby knife for harvesting split skin graft	Flexible nail set (for children's fractures)
	Mesher for split skin graft	Specific pelvic reduction clamps
	Traction pulleys	Electric or air powered dermatome for harvesting
	Braun frame for limb elevation and traction	split skin graft
	Vacuum assisted wound closure – 'home made' with	Vacuum assisted wound closure – company
	portable suction	purpose-made version
		Large femoral distractor
Tertiary provider		
Traction operating table	Small external fixator set (upper limb)	Power drill – handyman type (hardware store) with
Specialist radiolucent table	Rush nail set	sterile cover
C-arm image intensifier	K-wire and cerclage wiring set	Hand drill

Power drill - fully sterilisable Cable set with tensioners Manual plaster cast saw Power saw - fully sterilisable Flexible nail set (for children's fractures) ACL reconstruction equipment Electric plaster cast saw Total hip replacement set Gigli saw Total knee replacement set T handle Knee arthroscopy equipment Large basic orthopaedic set (including large size Small fragment plating set Large fragment plating set nibblers, bone cutters, osteotomes, mallet, forceps, Dynamic hip screw (DHS) instrument set retractors, needle holders) Hip hemiarthroplasty set Small basic orthopaedic set (including small size SIGN nailing set nibblers, bone cutters, osteotomes, toffee hammer, Tibial nail set (not SIGN) - locking forceps, retractors, needle holders) Femoral nail set (not SIGN) - locking Fine instrument soft tissue set (including small Femoral reconstruction nail set (not SIGN) forceps, needle holders etc. suitable for hand surgery Proximal femoral nail set (i.e., Gamma nail) and similar) Large cannulated screws Amputation set Small cannulated screws Large fracture reduction clamp set Mini fragment (hand) plating set Small fracture reduction clamp set Locking plating set (upper limb) Specific pelvic reduction clamps Locking plating set (lower limb) Humby knife for harvesting split skin graft Large external fixator set (lower limb) Electric or air powered dermatome for harvesting split skin graft Mesher for split skin graft Traction pulleys Braun frame for limb elevation and traction Vacuum assisted wound closure - 'home made' with portable suction Vacuum assisted wound closure - company purposemade version Large femoral distractor

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Table 2: Final list of essential and desirable equipment from Trauma and Orthopaedic care in LMICs.

Discussion

People in LMICs lack access to basic surgical care, and surgical systems remain severely under-resourced in these areas, despite evidence that surgical care can be cost effective and reduce mortality^{13 14}. By using the Delphi method, we recruited 20 experts, all of whom working LMICs, to come up with recommendations for a list of essential and desirable equipment for 3 different levels of care provider (non-operative based provider, specialist provider with operative fracture care and tertiary centre with operative fracture care and orthopaedics).

This study provides consensus recommendation on essential equipment for T&O care in LMICs. These recommendations will be useful for resource planning at different levels of T&O care. LMICs policy-makers and budget-providers can use these recommendations when planning current and future T&O care needs. These lists empower T&O providers to assess whether they have the essential equipment required at each provider institution. In many LMICs, T&O care is deficient at all levels of provider and faces resource limitations. Deficiencies include infrastructure, supplies and human resources $^{14-16}$. Spiegel *et al.* found availability of uninterrupted open treatment of fractures in hospitals with \leq 100 beds to be 17% 15 . We wanted our recommendations to be part of the broader work that is guiding allocation of resources required at different levels of care. Our study focuses on T&O equipment, which to date has been a neglected aspect of policy development.

The World Health Organisation (WHO) have guidelines for essential trauma care, although to date they have not produced an essential T&O equipment list such as that proposed in this study. They deemed immobilisation and splinting resources to be essential even at basic level of care. They stated the following procedures should be essential at tertiary and specialist hospitals with orthopaedic surgeons: closed manipulation and casting, skeletal traction, external fixation, internal fixation, irrigation and debridement of complex extremity wounds including open fractures. They also recognised other procedures need to be considered such as management of injured hands, tendon laceration, compartment syndrome and amputation. They stated the relevant equipment must not only be physically present but also promptly available to all who urgently need it. Any worn out or broken equipment must be repaired or replaced¹⁷.

WHO categorizes physical resources into diagnostic equipment, implants and operative equipment. We did not address implants in our study as we considered them to be consumables. We wanted to address operative equipment that can provide essential T&O care. We also did not look at diagnostic equipment except for a C-arm image intensifier for the operating theatres to enable some of the operations to be carried out safely. Our experts recommended the C-arm image intensifier as essential at the level of specialist and tertiary providers. For trauma care, WHO considers a C-arm image intensifier as a desirable resource due to cost constraints, otherwise they do recognise that this should be an essential equipment¹⁷.

All healthcare systems require constant monitoring and assessment to determine economics and outcomes. Healthcare should be evidence based. The impact of availability of essential equipment on outcomes, for example on the number of surgeries performed for those where surgery is indicated, requires audit in the future.

The equipment items listed are available from numerous commercial suppliers with different levels of quality and price. The exception in our list is the SIGN nail system¹⁸ and we allowed this exception

since this system is made available without cost for trained providers in LMICs. These lists provide a standard against which potential suppliers can tender, such that providers can make effective and affordable decisions. Our stratification of equipment needs for different levels of provider helps target funding at the correct level and can save waste in purchasing unnecessary equipment. Availability of advanced equipment in more basic care facilities not only wastes resources but can be dangerous, as staff in these facilities are not trained to use them correctly. It has also been shown that in LMICs, less than 50% of facilities had the capacity to repair or maintain equipment which again would a waste of resources for advanced equipment¹⁹. Equally trained surgeons treating complex injuries cannot do so safely unless they have the range of equipment specified in these lists. These lists thus promote both a focus in resource allocation, and a safety parameter.

Limitations

We recognise many limitations in this study. Several factors affect access to and quality of care for trauma patients. This study only looks at the need to agree on and provide appropriate equipment. In using the Delphi technique, we used the standard Delphi technique and not the modified technique which encompasses a face-to-face meeting between the experts. Our experts all came from Africa and the lists are designed for sub-Saharan Africa. Although they may have application across all LMICs, this has not been tested. We did not specify the number of each equipment item that would be required. Clearly this will depend on the volume of patient throughput at each institution. The three levels of service provider specified may not exactly be present in all health care systems in Africa. The definitions were devised by the senior author who has extensive experience in many African countries. Nevertheless, we accept that minor adjustment may be required to fit the lists to some health care systems.

Conclusion

These recommendations have the potential to improve T&O care in LMICs. The equipment lists proposed are reasonable and feasible for LMICs healthcare systems. Indeed, it should be questioned whether countries can afford not to care for injured persons in an appropriate and timely fashion.

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		Reporting Item	Page Number
	<u>#1</u>	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	4
	<u>#2</u>	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	<u>#3</u>	Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	<u>#4</u>	Purpose of the study and specific objectives or questions	3
Qualitative approach and research paradigm	<u>#5</u>	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and	4

4/5

NA

4/5

5

60

guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

Researcher characteristics and reflexivity

Sampling strategy

Context

Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability

Setting / site and salient contextual factors; rationale 4/5 #7

#8 How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale

Ethical issues pertaining to human subjects

Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues

5 Data collection methods #10 Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings;

rationale

#9

Data collection Description of instruments (e.g. interview guides, #11 instruments and questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed technologies over the course of the study

Units of study documents, or events included in the study; level of

#12 Number and relevant characteristics of participants,

participation (could be reported in results)

		participation (could be reported in results)	
Data processing	<u>#13</u>	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	4/5
Data analysis	<u>#14</u>	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	4/5
Techniques to enhance trustworthiness	<u>#15</u>	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	4/5
Syntheses and interpretation	<u>#16</u>	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	6
Links to empirical data	<u>#17</u>	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	
Intergration with prior work, implications, transferability and contribution(s) to the field	<u>#18</u>	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	9/10
Limitations	<u>#19</u>	Trustworthiness and limitations of findings	12
Conflicts of interest	<u>#20</u>	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	13
Funding	<u>#21</u>	Sources of funding and other support; role of funders in data collection, interpretation and reporting	13

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Essential fracture and orthopaedic equipment lists in low resource settings:

Consensus derived by survey of experts in Africa

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Abstract

Introduction: Low- and middle-income countries (LMICs) have a growing need for trauma and orthopaedic (T&O) surgical interventions but lack surgical resources. Part of this is due to the high amount of road traffic accidents in LMICs. We aimed to develop recommendations for an essential list of equipment for three different levels of care providers.

Methods: The Delphi method was used to achieve consensus on essential and desirable T&O equipment for LMICs. Twenty experts with T&O experience from LMICs underwent two rounds of questionnaires. Feedback was given after each round of questionnaires. The 1st round of questionnaire consisted of 45 items graded on a Likert scale with the 2nd round consisting of 50 items. We used an electronic questionnaire to collect our data for 3 different levels of care: non-operative based provider, specialist provider with operative fracture care and tertiary provider with operative fracture care and orthopaedics.

Results: After two rounds of questionnaires, recommendations for each level of care in LMICs included four essential equipment items for non-operative based providers; 27 essential equipment items for specialist providers with operative fracture care, and 46 essential equipment items for tertiary providers with operative fracture care and orthopaedic care.

Conclusion: These recommendations can facilitate in planning of appropriate equipment required in an institution which in turn has the potential to improve the capacity and quality of T&O care in LMICs. The essential equipment lists provided here can help direct where funding for equipment should be targeted. Our recommendations can help with planning and organising national T&O care in LMICs to achieve appropriate capacity at all relevant levels of care.

Strengths of this study

- Our experts are all from Africa with expertise in working in LMIC, therefore, able to give the breadth and depth of experience needed to assess which equipment are reasonable and essential.
- The Delphi technique was used to achieved consensus in a highly structured and controlled manner.

Limitations of this study

- Multiple factors affect access to, and quality of care, for trauma patients and this study only looks at the need to agree on and provide appropriate equipment.
- We did not specify the number of each equipment item that would be required as this can vary between institutions.
- We used the standard Delphi technique and not the modified technique which encompasses a face-to-face meeting between the experts.

Introduction

Surgery is an essential component of health care. Two thirds of the world's population do not have access to safe, affordable and timely surgical care and 16.9 million people die from conditions that require surgical care each year. Most of these deaths are from low-income and middle-income countries (LMICs)¹². From the World Health Organisation (WHO) global health observatory data, LMICs had higher road traffic fatality rates per 100,000 population (24.1 and 18.4 respectively) compared to high-income countries (9.2)³. Trauma kills more people than HIV/AIDS, malaria and tuberculosis combined³. Injuries are mainly from road traffic accidents, and disproportionately affect the young population⁴.

For every death from injury, many more people are living with disability, contributing to the vicious cycle of poverty and reduced productivity^{3 5}. Considerable mortality and morbidity can be avoided with prompt and appropriate trauma and orthopaedic care. Lower extremity injury can be a devastating event in LMICs due to reduced access to modern orthopaedic care. Chagomerana *et al.* found a mortality rate of 9.0% in patients treated with traction and a mortality rate of 1.3% in patients treated with surgery in Malawi⁶. If all-cause-injury mortality can be reduced to the level in high-income countries, 50 million disability adjusted life years (DALYs) and \$786 billion could be saved annually⁴.

Some programmes have been introduced to improve road safety, along with education and training of health professionals, and these have addressed some of the inequality issues. However, further work is needed to explore what resources are required to provide trauma and orthopaedic (T&O) care in LMICs⁷. Stephens *et al.* found only 58% of patients admitted with the intention of definitive T&O surgical care received surgery due to resource constraints⁸. Deficient surgical equipment and supplies often limit access to surgical care. The WHO guidelines for essential trauma care has also recognised the need for a specific equipment list⁹.

There is a lack of recommendation on what essential equipment is required in health care systems with limited resources. This may lead to absence of equipment, or acquisition of inappropriate equipment. Without the provision of appropriate equipment, training of national T&O surgeons and other healthcare providers can be wasteful as they are disempowered from caring for the injured by lack of equipment. To address this gap, we wanted to provide an expert consensus on the essential equipment that is required to provide T&O care at different levels of surgical providers in LMICs.

Aim

We aimed to produce a reference list of essential and desirable equipment for T&O providers in LMICs. The list is intended to guide governments, healthcare providers, and donors regarding the necessary equipment to be able to provide timely and appropriate care of fractures and orthopaedic conditions encountered at facilities in LMICs in sub-Saharan Africa. Similar principles are likely to apply in LMICs outside Africa. This list will be a core set of equipment required, as well as a list of desirable but not essential equipment, to give care providers advice on further useful equipment if they can go beyond the core essentials. We hoped these lists will be available for all those who participate in the supply chain management. We provided a generic list with no company affiliation and allow health providers to purchase from companies in their range of affordability.

Method

We used the Delphi method for this study to generate a consensus statement of essential equipment for T&O care at different levels of care^{10 11}. The Delphi method is used to elicit consensus on a given topic. A two-round Delphi study was used with a group of experts answering two webbased questionnaires through Google forms¹². The timing between the two questionnaires was 30 days¹³.

We provided the experts with definitions of what we mean by equipment, essential equipment and desirable equipment.

Definitions

<u>'Equipment'</u> is a re-useable item which facilitates fracture and orthopaedic care, and is specific to T&O. We did not consider hospital furniture items unless they were specific to T&O care – for example a traction table for fracture surgery was included, but an operating table was not. We did not list consumable items, but some equipment listed requires appropriate consumables and it was understood that a supply of appropriate consumables would be required.

<u>'Essential equipment'</u> is an item of equipment considered to be essential by 75% or more of the experts who responded.

<u>'Desirable equipment'</u> is an item for which does not reach consensus for being an essential equipment but does achieve 75% or more when considering 'definitely' or' possibly include' together.

Three independent experts, each with over 15 years' experience in Trauma and Orthopaedic (T&O) surgery were asked to verify the definitions used for different levels of provider institution, and to generate a list of possible essential equipment for selection in the questionnaire. Definitions used for each tier of provider were as listed below:

Tiers of provider

<u>'Non-operative based provider'</u>: such a centre would not have a specialist T&O surgeon, but care would be given by general doctors or paramedics such as Orthopaedic Clinical Officers (OCOs).

<u>'Specialist provider with operative fracture care'</u>: such a centre would have 1 to 3 T&O or General surgeons with specific training in operative fracture care. It may receive residents but would not oversee its own residency programme in T&O.

<u>'Tertiary provider with operative fracture care and orthopaedics':</u> such a centre would be a referral centre for T&O and a resident teaching centre as well. It would normally be staffed by 4 or more specialist T&O surgeons, with some available sub-specialty expertise (pelvic & acetabulum, hand surgery, etc.).

Spine and craniomaxillofacial (CMF) surgery were omitted as their inclusion would have been too broad.

A group of 34 trained T&O surgeons in Africa who serve regularly as faculty on fracture care education courses in LMICs were invited to answer the questionnaire. These selected experts work in 13 sub-Saharan African (SSA) countries. Eighteen works at a tertiary hospital level and 15 at specialist provider level. From round 1, we received 23 responses from 11 different African countries. The respondents included 52% from specialist tertiary centres and 48% of respondents from specialist provider centres. We received 20 expert responses in round 2 from 10 different countries. The round 2 respondents included 55% from specialist tertiary centres and 45% of respondents from specialist provider centres.

The questionnaire was designed by one of the authors (WJH) who has 20 years of experience of T&O surgery in LMICs. The responses were analysed by YC who has no previous experience of or connections with T&O surgery in LMICs but is familiar with the Delphi technique. The responders were anonymous but were requested to identify their country of regular work. Experts were each assigned a number and kept their number throughout the process.

We sent out a web-based questionnaire explaining our aims and instructions as follows:

'Our aim is to produce an essential equipment list for fracture care and orthopaedic provider institutions. Please mark your preference from 'definitely exclude' to 'definitely include', against each equipment item for each of the three tiers of care-provider. It should be assumed that equipment would be accompanied by appropriate implants/consumables with an ongoing supply. Please do not leave any blanks. There is free text space where you can give suggestions of other essential equipment or indicate any questions that are not clear as well as to give reasoning for your response. If your response is neutral, please provide further feedback as to why.

The responses were graded by the experts on a 5-point Likert scale¹³. The options on the scale were as follows: definitely exclude, possible exclude, neutral, possibly include, definitely include. 'Possibly include' and 'definitely include' were counted towards consensus. Responses 'definitely exclude' and 'possibly exclude' counted towards an item being dropped.

Items which did not fulfil either criterion of definitely include or definitely exclude were brought forward to the next phase with specific feedback on the lack of consensus reached for the item to try and clarify consensus. Thus, in round two the same questionnaire was proposed to the expert group minus all items which had 75% of experts selecting 'definitely exclude'. In addition, experts were now given feedback regarding which items had so far achieved 75% consensus for inclusion. The experts could select differently in the second round as their 'final decision' with the benefit of allowing the experts to narrow down the essential equipment based on the feedback after round 1.

Quantitative data including the mean, median and the frequency distribution of each option for each item were sent to the participants after round 1. Thus, participants were able to see which items were heading towards being included in the essential or desirable equipment list as well as which items were going to be dropped. In round 2, we specifically named which additional items were added from the expert suggestions after round 1.

After round 2, any items still left neutral at this point were now dropped. Items which reached 75% 'definitely include' were classed as essential equipment. Any item which did not reach 75% 'definitely include' but reached 75% consensus when 'definitely include' and 'possibly include' were counted together contributed to a list of desirable but not essential equipment. Equipment items for which opinion was sought have been listed on the main result table (see Table 1).

Patient and public involvement

No patient or public involvement was required in this study.

Results

Results from round 1

All the items were carried forward to the second round in the specialist provider and tertiary centre tiers of care. Only the non-operative based provider had 16 items excluded from round 1. We included 5 additional items for round 2 voting. These are shown as the last 5 equipment items in table 1.

Results from round 2

The final list of essential and desirable equipment for each tier is shown in table 2. For the non-operative provider, the essential equipment related to things that are required for non-operative treatment such as traction and plaster casts. Essential equipment for the specialist provider included equipment for operative intervention, such as the small fragment set, large fragment set, SIGN/rush nailing, external fixators, K wiring set as well as large cannulated screws. It did not include the full complement of surgical kit offered for selection as these centres are less likely to be performing the full complement of surgical interventions. The majority of equipment for selection was recommended as essential for a tertiary provider with the remaining 3 equipment being listed as desirable. The essential equipment for tertiary provider included total hip and knee sets as well as reduction clamps for pelvic operations as these centres would potentially be able to offer these types of operations.

Items included in questionnaire	Non-	Specialist	Tertiary
	operative	provider	provider
	provider		
 Traction operating table 	N	D	E
2. C-arm image intensifier	N	E	E
3. Power drill - fully sterilisable	N	Е	E
4. Power saw - fully sterilisable	N	D	E
5. Power drill - handyman type	N	E	D
(hardware store) with sterile			
cover			
6. Hand drill	D	D	D
7. Thandle	D	E	E
8. Small fragment plating set	N	Е	E
9. Large fragment plating set	N	E	E
10. Dynamic hip screw (DHS)	N	E	E
instrument set			
11. Hip hemiarthroplasty set	N	D	E
12. SIGN nailing set	N	E	E

13. Tibial nail set (not SIGN) – locking	N	D	E
14. Femoral nail set (not SIGN) –	N	D	E
locking			_
15. Femoral reconstruction nail set (not SIGN)	N	D	E
16. Proximal femoral nail set (i.e.,	N	D	E
Gamma nail)			
17. Large cannulated screws	N	E	E
18. Small cannulated screws	N	D	E
19. Mini fragment (hand) plating set	N	D	E
20. Locking plating set (upper limb)	N	D	E
21. Locking plating set (lower limb)	N	D	E
22. Large external fixator set	N	E	E
(lower limb)			
23. Small external fixator set	N	E	E
(upper limb)			
24. Rush nail set	N	E	E
25. K-wire and cerclage wiring set	N	E	E
26. Cable set with tensioners	N	D	E
27. Flexible nail set (for children's	N	D	E
fractures)			
28. Total hip replacement set	N	N	E
29. Total knee replacement set	N	N	E
30. Knee arthroscopy equipment	N	N	E
31. ACL reconstruction equipment	N	N	D
32. Large basic orthopaedic set	N	E	E
(including large size nibblers,			
bone cutters, osteotomes,			
mallet, forceps, retractors,			
needle holders)			
33. Small basic orthopaedic set	N	E	E
(including small size nibblers,			
bone cutters, osteotomes,			
toffee hammer, forceps,			
retractors, needle holders)			
34. Fine instrument soft tissue set	N	E	E
(including small forceps,			
needle holders etc. suitable for			
hand surgery and similar)	N.I.		
35. Large fracture reduction clamp set	N	E	E
36. Small fracture reduction clamp	N	E	E
set			_
37. Specific pelvic reduction clamps	N	D	E
38. Humby knife for harvesting	N	E	Е
split skin graft			
		-	

39. Electric or air powered dermatome for harvesting split skin graft	N	D	E
40. Mesher for split skin graft	N	E	E
41. Traction pulleys	E	E	E
42. Braun frame for limb elevation and traction	E	E	E
43. Vacuum assisted wound closure – 'home made' with portable suction	N	E	E
44. Vacuum assisted wound closure – company purpose-made version	N	D	E
45. Large femoral distractor	N	D	E
46. Specialist radiolucent operating table	N	D	E
47. Electric plaster saw	E	E	E
48. Manual plaster saw	E	E	D
49. Gigli saw	N	E	E
50. Amputation set	N	Е	E

Table 1: Results after round 2 (N=not recommended; E=essential; D=desirable; blue highlighted items were added after round 1; grey highlighted items were excluded after round 1)

Essential equipment list		Desirable equipment list
Non-operative provider		
Electric plaster cast saw		Hand drill
Manual plaster cast saw		T handle
Traction pulleys		
Braun frame for limb elevation and traction		
Specialist provider		
C-arm image intensifier	Rush nail set	Traction operating table
Power drill - fully sterilisable	K-wire and cerclage wiring set	Specialist radiolucent table
Power drill – handyman type (hardware store) with	Large basic orthopaedic set (including large size	Power saw - fully sterilisable
sterile cover	nibblers, bone cutters, osteotomes, mallet, forceps,	Hand drill
Electric plaster cast saw	retractors, needle holders)	Hip hemiarthroplasty set
Manual plaster cast saw	Small basic orthopaedic set (including small size	Tibial nail set (not SIGN) - locking
Gigli saw	nibblers, bone cutters, osteotomes, toffee hammer,	Femoral nail set (not SIGN) - locking
T handle	forceps, retractors, needle holders)	Femoral reconstruction nail set (not SIGN)
Small fragment plating set	Fine instrument soft tissue set (including small	Proximal femoral nail set (i.e., Gamma nail)
Large fragment plating set	forceps, needle holders etc. suitable for hand surgery	Small cannulated screws
Dynamic hip screw (DHS) instrument set	and similar)	Mini fragment (hand) plating set
SIGN nailing set	Amputation set	Locking plating set (upper limb)
Large cannulated screws	Large fracture reduction clamp set	Locking plating set (lower limb)
Large external fixator set (lower limb)	Small fracture reduction clamp set	Cable set with tensioners
Small external fixator set (upper limb)	Humby knife for harvesting split skin graft	Flexible nail set (for children's fractures)
	Mesher for split skin graft	Specific pelvic reduction clamps
	Traction pulleys	Electric or air powered dermatome for harvesting
	Braun frame for limb elevation and traction	split skin graft
	Vacuum assisted wound closure – 'home made' with	Vacuum assisted wound closure – company
	portable suction	purpose-made version
		Large femoral distractor
Tertiary provider		
Traction operating table	Small external fixator set (upper limb)	Power drill – handyman type (hardware store) wi
Specialist radiolucent table	Rush nail set	sterile cover

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C-arm image intensifier K-wire and cerclage wiring set Hand drill Power drill - fully sterilisable Manual plaster cast saw Cable set with tensioners Power saw - fully sterilisable Flexible nail set (for children's fractures) ACL reconstruction equipment Electric plaster cast saw Total hip replacement set Total knee replacement set Gigli saw T handle Knee arthroscopy equipment Small fragment plating set Large basic orthopaedic set (including large size Large fragment plating set nibblers, bone cutters, osteotomes, mallet, forceps, Dynamic hip screw (DHS) instrument set retractors, needle holders) Small basic orthopaedic set (including small size Hip hemiarthroplasty set nibblers, bone cutters, osteotomes, toffee hammer, SIGN nailing set Tibial nail set (not SIGN) - locking forceps, retractors, needle holders) Femoral nail set (not SIGN) - locking Fine instrument soft tissue set (including small Femoral reconstruction nail set (not SIGN) forceps, needle holders etc. suitable for hand surgery Proximal femoral nail set (i.e., Gamma nail) and similar) Large cannulated screws Amputation set Large fracture reduction clamp set Small cannulated screws Mini fragment (hand) plating set Small fracture reduction clamp set Locking plating set (upper limb) Specific pelvic reduction clamps Locking plating set (lower limb) Humby knife for harvesting split skin graft Large external fixator set (lower limb) Electric or air powered dermatome for harvesting split skin graft Mesher for split skin graft Traction pulleys Braun frame for limb elevation and traction Vacuum assisted wound closure - 'home made' with portable suction Vacuum assisted wound closure - company purposemade version Large femoral distractor

Table 2: Final list of essential and desirable equipment from Trauma and Orthopaedic care in LMICs.

Discussion

People in LMICs lack access to basic surgical care, and surgical systems remain severely under-resourced in these areas, despite evidence that surgical care can be cost effective and reduce mortality^{14 15}. By using the Delphi method, we recruited 20 experts, all of whom working LMICs, to come up with recommendations for a list of essential and desirable equipment for 3 different levels of care provider (non-operative based provider, specialist provider with operative fracture care and tertiary centre with operative fracture care and orthopaedics).

This study provides consensus recommendation on essential equipment for T&O care in LMICs. These recommendations will be useful for resource planning at different levels of T&O care. LMIC policy-makers and budget-providers can use these recommendations when planning current and future T&O care needs. These lists empower T&O providers to assess whether they have the essential equipment required at each provider institution. In many LMICs, T&O care is deficient at all levels of provider and faces resource limitations. Deficiencies include infrastructure, supplies and human resources $^{15-17}$. Spiegel *et al.* found availability of uninterrupted open treatment of fractures in hospitals with ≤ 100 beds to be $17\%^{16}$. We wanted our recommendations to be part of the broader work that is guiding allocation of resources required at different levels of care. Our study focuses on T&O equipment, which to date has been a neglected aspect of policy development.

The WHO guidelines for essential trauma care recognised the need for an equipment list but they do not have an essential T&O equipment list such as the one that is proposed in this study within their guidelines⁹. They deemed immobilisation and splinting resources to be essential even at basic level of care. They stated the following procedures should be essential at tertiary and specialist hospitals with orthopaedic surgeons: closed manipulation and casting, skeletal traction, external fixation, internal fixation, irrigation and debridement of complex extremity wounds including open fractures. They also recognised other procedures need to be considered such as management of injured hands, tendon laceration, compartment syndrome and amputation. They stated the relevant equipment must not only be physically present but also promptly available to all who urgently need it. Any worn out or broken equipment must be repaired or replaced.

WHO categorizes physical resources into diagnostic equipment, implants and operative equipment. We did not address implants in our study as we considered them to be consumables. We wanted to address operative equipment that can provide essential T&O care. We also did not look at diagnostic equipment except for a C-arm image intensifier as this is required to enable some of the operations to be carried out safely within the operating theatres.

We have recommended that equipment for casting and traction as essential for non-operative care providers, however WHO guidelines for essential care recommendations are mainly for the initial management of trauma particular immobilisation and initial haemorrhage control. They have recommended closed reduction and skeletal traction as something that is possibly required at the non-operative level. We did not look at the equipment required for the initial management of trauma but more specifically at the management of orthopaedic trauma beyond the initial management. For a specialist level provider, they have recommended all the surgical procedures including closed reduction, skeletal traction, wound management, internal and external fixation, hand debridement/fixation and tendon repair as essential.

Our essential equipment for specialist providers would cover all these procedures. Only one procedure they listed as desirable which is fasciotomy for compartment syndrome although this procedure can be covered with a basic surgical set. Dealing with the sequalae after the initial fasciotomy may require more specialist equipment such as a VAC dressing or skin grafting which we have listed as part of our essential equipment for specialist providers. A specialist provider would have an orthopaedic surgeon and general surgeons particularly those with expertise in vascular surgery would be able to diagnose and perform fasciotomies if required and therefore we feel that equipment for fasciotomy should be available.

At tertiary level, the majority of operative intervention should be available and both the WHO list of procedures of which resources should be available and our equipment list reflects this. One point we partially disagree on is the need for image intensifier. WHO has stated it is desirable, whereas, we feel that it is essential. However, their decision for this is due to cost constraints, otherwise they do recognise that an image intensifier should be an essential equipment⁹. Manufacturers in middle income countries can now provide such equipment at vastly reduced costs and thus we feel an image intensifier should be an essential equipment.

All healthcare systems require constant monitoring and assessment to determine economics and outcomes. Healthcare should be evidence based. The impact of availability of essential equipment on outcomes, for example on the number of surgeries performed for those where surgery is indicated, requires audit in the future.

The equipment items listed are available from numerous commercial suppliers with different levels of quality and price. The exception in our list is the SIGN nail system¹⁸ and we allowed this exception since this system is made available without cost for trained providers in LMICs. These lists provide a standard against which potential suppliers can tender, such that providers can make effective and affordable decisions. Our stratification of equipment needs for different levels of provider helps target funding at the correct level and can save waste in purchasing unnecessary equipment.

Availability of advanced equipment in more basic care facilities not only wastes resources but can be dangerous, as staff in these facilities are not trained to use them correctly. It has also been shown that in LMICs, less than 50% of facilities had the capacity to repair or maintain equipment which again would be a waste of resources for advanced equipment¹⁹. Equally, trained surgeons treating complex injuries cannot do so safely unless they have the range of equipment specified in these lists. These lists thus promote both a focus in resource allocation, and a safety parameter.

Limitations

We recognise several limitations in this study. Multiple factors affect access to, and quality of care, for trauma patients. This study only looks at the need to agree on and provide appropriate equipment. In using the Delphi technique, we used the standard Delphi technique and not the modified technique which encompasses a face-to-face meeting between the experts. Our experts all came from Africa and the lists are designed for sub-Saharan Africa. Although they may have application across all LMICs, this has not been tested. We did not specify the number of each equipment item that would be required. Clearly this will depend on the volume of patient throughput at each institution. The three levels of service provider specified may not exactly be present in all health care systems in Africa. The definitions were devised by the senior author who

has extensive experience in many African countries. Nevertheless, we accept that minor adjustment may be required to fit the lists to some health care systems.

Conclusion

These recommendations have the potential to improve T&O care in LMICs. The equipment lists proposed are reasonable and feasible for LMICs healthcare systems. Indeed, it should be questioned whether countries can afford not to care for injured persons in an appropriate and timely fashion.

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- 8. Dr Deo Manyama, Tanzania
- 9. Dr Joseph Mwanga, Tanzania
- 10. Dr Boston Munthali, Malawi
- 11. Dr Prem Yohannan, Mozambique
- 12. Dr John Ekure, Uganda
- 13. Dr Henry Ndasi, Cameroon.
- 14. Dr James Munthali, Zambia
- 15. Dr Samuel Maina, Malawi
- 16. Dr Foster Amponsah, Ghana
- 17. Dr Kevin Lakati, Kenya
- 18. Dr Yirga Mnewer, Ethiopia
- 19. Dr Francis Mbugua, Kenya
- 20. Dr Kebba Marenah, Gambia

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Trial registration: Not applicable

Data Sharing Statement: Questionnaire and data from questionnaire are available upon request.

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Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

		Reporting Item	Page Number
	<u>#1</u>	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g. ethnography, grounded theory) or data collection methods (e.g. interview, focus group) is recommended	4
	<u>#2</u>	Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Problem formulation	<u>#3</u>	Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	3
Purpose or research question	<u>#4</u>	Purpose of the study and specific objectives or questions	3
Qualitative approach and research paradigm	<u>#5</u>	Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenolgy, narrative research) and	4

guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. The rationale should briefly discuss the justification for choosing that theory, approach, method or technique rather than other options available; the assumptions and limitations implicit in those choices and how those choices influence study conclusions and transferability. As appropriate the rationale for several items might be discussed together.

Researcher characteristics and reflexivity

Researchers' characteristics that may influence the research, including personal attributes, qualifications / experience, relationship with participants, assumptions and / or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and / or transferability

4/5

4/5

NA

Context

#7 Setting / site and salient contextual factors; rationale

Sampling strategy #8 How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling

saturation); rationale

Ethical issues pertaining to human subjects

#9 Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues

Data collection methods

#10 Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources / methods, and modification of procedures in response to evolving study findings; rationale

Data collection instruments and technologies

#11 Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study

Units of study #12 Number and relevant characteristics of participants, documents, or events included in the study; level of

participation (could be reported in results)

		participation (costila to reported in recents)	
Data processing	<u>#13</u>	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	4/5
Data analysis	<u>#14</u>	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale	4/5
Techniques to enhance trustworthiness	<u>#15</u>	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation); rationale	4/5
Syntheses and interpretation	<u>#16</u>	Main findings (e.g. interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	6
Links to empirical data	<u>#17</u>	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings	
Intergration with prior work, implications, transferability and contribution(s) to the field	<u>#18</u>	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application / generalizability; identification of unique contributions(s) to scholarship in a discipline or field	9/10
Limitations	<u>#19</u>	Trustworthiness and limitations of findings	12
Conflicts of interest	<u>#20</u>	Potential sources of influence of perceived influence on study conduct and conclusions; how these were managed	13
Funding	<u>#21</u>	Sources of funding and other support; role of funders in data collection, interpretation and reporting	13

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